

## IN THE CLAIMS:

Please amend the claims as follows:

1. **(Original)** A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, characterized in that the pharmaceutical composition has enhanced oral bioavailability.
2. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone used is a pharmaceutically acceptable solubility-improved form.
3. **(Original)** A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is micronised metaxalone.
4. **(Original)** A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is a salt form of metaxalone.
5. **(Original)** A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is a high-energy crystalline form of metaxalone.
6. **(Original)** A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is amorphous metaxalone.
7. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the composition comprises a mixture of metaxalone and a solubilizing agent.
8. **(Original)** A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value between 10 and 40 $\mu$ m, 90% undersize value between 6 and 30 $\mu$ m, and 50% undersize value between 3 and 10 $\mu$ m, characterised in that the pharmaceutical composition has enhanced oral bioavailability.
9. **(Original)** A pharmaceutical composition as claimed in claim 8, wherein the metaxalone used has specific surface area per unit volume of more than 1.5m<sup>2</sup>/cm<sup>3</sup>.
10. **(Original)** A pharmaceutical composition as claimed in claim 9, wherein the metaxalone used has specific surface area per unit volume of more than 2.5m<sup>2</sup>/cm<sup>3</sup>.

11. **(Original)** A pharmaceutical composition as claimed in claim 10, wherein the metaxalone used has specific surface area per unit volume of more than  $3.0\text{m}^2/\text{cm}^3$ .

12. **(Original)** A pharmaceutical composition as claimed in claim 8, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of  $40\mu\text{m}$ , 90% undersize value of  $30\mu\text{m}$ , and 50% undersize value of  $10\mu\text{m}$ .

13. **(Original)** A pharmaceutical composition as claimed in claim 12, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of  $30\mu\text{m}$ , 90% undersize value of  $14\mu\text{m}$ , and 50% undersize value of  $6\mu\text{m}$ .

14. **(Original)** A pharmaceutical composition as claimed in claim 13, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of  $10\mu\text{m}$ , 90% undersize value of  $5\mu\text{m}$ , and 50% undersize value of  $3\mu\text{m}$ .

15. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the amount of metaxalone used is in the range of 400mg to 1600mg.

16. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically acceptable excipient includes a wetting agent.

17. **(Original)** A pharmaceutical composition as claimed in claim 16, wherein the wetting agent used is a surfactant.

18. **(Original)** A pharmaceutical composition as claimed in claim 17, wherein the surfactant used is sodium lauryl sulfate.

19 – 22 **(Cancelled)**

23. **(Original)** A pharmaceutical composition as claimed in claim 1 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative,

PCT/IN2003/000294

biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.

24. **(Original)** A pharmaceutical composition as claimed in claim 8 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.

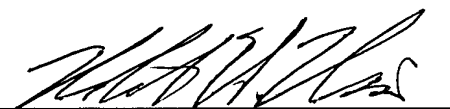
25 – 26 **(Cancelled)**

#### REMARKS

The above amendments are editorial changes to put the claims of the above-identified international application in compliance with the U.S. practice.

Respectfully submitted,  
BANNER & WITCOFF, LTD

Date: March 2, 2005

By: 

Robert H. Resis, Reg. No. 32,168

Ten South Wacker Drive  
Chicago, Illinois 60606-7407  
(312) 463-5000